



PATENT

Attorney Docket No. 00537/149003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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IN RE APPLICATION OF:
M. Culler et al.

EXAMINER: **TELLER, ROY**
ART UNIT: **1654**

TECH CENTER 1600/290C

APPLICATION NO.: **09/761,605**

FILED: **JANUARY 16, 2001**

FOR: **METHOD OF INHIBITING FIBROSIS
WITH A SOMATOSTATIN AGONIST**

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Date of Deposit Nov. 17, 2003

Dawn M. Janelle
Dawn M. Janelle

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY UNDER 37 C.F.R. §1.113

This reply (hereinafter "instant reply") is submitted in response to the Office Action mailed May 16, 2003, in respect of the above-captioned patent application, (hereinafter "instant application"), the period for response thereto having been extended to expire on November 16, 2003, pursuant to a Petition for Extension of Time, filed herewith. As November 16, 2003 falls on a Sunday, the instant reply is being timely filed on Monday, November 17, 2003.

REMARKS

Reconsideration of the Office Action mailed May 16, 2003, (hereinafter "instant Office Action"), and withdrawal of the rejection of claims 142 and 143 are respectfully requested.

In the instant Office Action, claims 142-143 are listed as pending and claims 142-143 are listed as rejected.

Applicants hereby incorporate by reference in their entirety previous arguments made of record in their communications filed

on March 15, 2002 and March 3, 2003 (hereinafter "first response" and "previous response," respectively).

Claim Rejections - 35 U.S.C. §112, First Paragraph

The Examiner has maintained the rejection of claims 142 and 143 under 35 U.S.C. §112, first paragraph, for the reasons stated at pages 2 - 4 of the Office Action mailed August 26, 2002 (hereinafter "previous Office Action"). Applicants respectfully traverse this rejection.

In the previous Office Action, the Examiner alleged that this rejection included an objection under 35 U.S.C. §132 concerning the amendments offered by Applicants in Applicants' first response.

Applicants' understanding of the objection taken as a whole is that the proviso amended to claim 142, "provided said fibrosis is not in the kidney, in the lung, ... and further provided that said fibrosis is not periportal fibrosis", allegedly introduces new matter into the claim; i.e., claim 142 as amended is not supported by the written description of the instant application. In the previous Office Action, the Examiner cited several passages in the instant application which allegedly limit the scope of the disclosed invention. (See page 3, lines 8-9 of the previous Office Action.) In the previous response, Applicants requested that the Examiner explicitly define the nonsupported subject matter of the pending claims. (See previous response, page 3, lines 10-11.) As this inquiry remains unanswered, Applicants once again respectfully request an explicit definition of the subject matter of the claims not described in the instant application.

Request for clarification notwithstanding, Applicants respectfully maintain that the foregoing proviso does not introduce new matter and that all of the subject matter covered

by claim 142, as presently amended, is disclosed in the instant application. The Examiner is respectfully requested to reconsider the following passage found on page 2, lines 25-31 of the instant application:

In one aspect, this invention provides a method of inhibiting fibrosis in a patient, said method comprising administering a therapeutically effective amount of somatostatin or a somatostatin agonist to said patient; a method which is preferred of the foregoing method is wherein said method comprises administering a therapeutically effective amount of a somatostatin agonist to said patient.

Thus, disclosed in the instant application is a method of inhibiting fibrosis in a patient, without limitation with respect to the location of the fibrosis within the body. The Examiner is respectfully reminded that specific passages disclosing treatment of fibrosis in the body were provided in the previous response. (See pages 3-4 of the previous response.) Indeed, the proviso amended to claim 142 provides a limitation of the subject matter of the claim by distinctly excluding specific organs and tissues, namely, the kidney, the lung, the liver, the skin, the central nervous system, bone or bone marrow, the cardiovascular system, an endocrine organ, and the gastrointestinal system. The proviso was entered merely to avoid overlap with subject matter which was already claimed in U.S. Patent No. 6,268,342; i.e., the patent which issued from the parent application of the instant application.

Thus, the subject matter of claim 142 as presently amended in no way contains subject matter which was not described in the instant application. Applicants respectfully request withdrawal of the rejection of the pending claims under 35 U.S.C. §112, First Paragraph, and the related objection under 35 U.S.C. §132.

B. Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner has maintained the rejection of claims 142 and 143 as being indefinite for allegedly failing to define where the fibrosis is located. Applicants respectfully traverse this rejection.

Applicants maintain that the limitation in claim 142 wherein the fibrosis occurs "in a patient" and the exclusion of specific tissues and organ systems sufficiently identifies the location of the fibrosis as to enable a skilled artisan to practice the invention.

Furthermore, contrary to the Examiner's contention that the limits of the invention are defined by the embodiments of the invention disclosed on pages 22-23 of the instant application, Applicants respectfully maintain that said embodiments are merely and explicitly illustrative. As stated on page 21, line 31, to page 22, line 1, of the instant application:

The following specific embodiments are...to be construed as merely illustrative, and not limitative of the remainder of the disclosure in any way whatsoever.
[Emphasis added.]

Thus, one skilled in the art is fully aware that the embodiments on pages 22-23 of the instant application serve as mere examples of tissues and organ systems in which fibrosis may occur. Importantly, as of the filing date of the parent application to which the instant application claims priority, the scientific and medical literature were replete with reports of research and clinical studies of the occurrence of fibrosis in virtually every tissue in the body. Applicants performed a cursory search of the PubMed database, accessed online through the National Center for Biotechnology Information (NCBI) of the U.S. National Library of Medicine (<http://www.ncbi.nlm.nih.gov/>), to identify studies of fibrosis published prior to the filing date of the parent application. For the Examiner's reference, submitted herewith in the attached appendix ("Appendix A") is a

small sampling of the abstracts of the publications obtained. Significantly, the references are representative of the occurrence of fibrosis in various tissues and organ systems induced by agents disclosed in the instant application. (See page 23, line 17, to page 24, line 21.) Applicants respectfully submit that the teachings of the instant application provide ample guidance to one skilled in the art to practice the invention as of the priority date.

Applicants respectfully suggest that the Examiner, by contending that the embodiments of the invention on pages 22-23 of the instant application should be construed as limitations on the invention, has erroneously imposed an unduly restrictive reading of the cited passage. Each of the tissues and organ systems is disclosed as an example, wherein the plain meaning and commonly accepted use of the word, "example" is understood. Significantly, the Examiner has not put forth a reasoned statement specifying why such a limited reading of the application should be adopted.

As requested in the previous response, Applicants respectfully request that the Examiner indicate with specificity how "[t]he negative limitations ... prevent[s] the operation of the invention *in vivo*", for example, by citing authority for the proposition that claims to a method of treatment of a physiologically diffuse disorder, such as fibrosis, must be limited to specifically exemplified tissue types. In the absence of such a showing, Applicants respectfully submit that the rejection under under 35 U.S.C. §112, second paragraph, is not supported.

Accordingly, Applicants respectfully request that the rejection of claims 142 and 143 under 35 U.S.C. §112, second paragraph be withdrawn.

Claim Rejections - Double Patenting

Applicants gratefully acknowledge withdrawal of the double patenting rejection of claims 142 and 143 in the instant Office Action.

Conclusion

Based upon the foregoing, Applicants respectfully submit that claims 142 and 143, as presently amended, are in condition for allowance. Prompt and favorable action is earnestly solicited.

Respectfully submitted,

Date: November 17, 2003

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